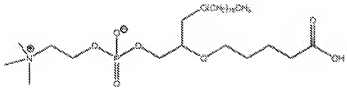
DETAILED ACTION

1. Claims 91-199 are pending in the application.

Responses to Election/Restriction

2. Applicant's election with traverse without arguments of Group I claims 91-199, in part, in the reply filed April 08, 2010 is acknowledged. Election of a compound of, i.e.,



, as the single species is also acknowledged.

Claims 91-199 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 91-199, in part, drawn to compounds of formula (I) and their methods of use thereof

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list

individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 91-199, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 91-199, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and therefore is made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 140-178 and 193-199 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inflammation using oxidized lipid compounds of Formula (I), does not reasonably provide enablement for preventing inflammation using oxidized lipid compounds without limitation (i.e., no named compounds or formula), see claim 140. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Dependent claims 141-178

and 193-199 are also rejected along with claim 140 under 35 U.S.C. 112, first paragraph.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is treating or preventing inflammation using oxidized lipid compounds without limitation (i.e., no named compounds or formula), see claim 140.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in*

vitro and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Baido et al. US 5,061,626 disclose a similar oxidized lipid, see columns 1-3.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833,166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming treating or preventing inflammation using oxidized lipid compounds, which are not limited. As such, the specification fails to enable the skilled artisan to use the oxidized lipid compounds for treating or preventing inflammation without limitation. In addition, there is no proof that the claimed oxidized lipid compounds to prevent inflammation, in a human or to an animal model.

In addition, there is no established correlation between *in vitro* activity and accomplishing preventing inflammation without limitation of the oxidized lipid compounds, *in vivo*, and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art

would not be able to use the instant oxidized lipid compounds since there is no description of an actual method wherein oxidized lipid compounds without limitation in a host is treated or prevented.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the instant compounds of the claims due to the unpredictability of the treatment or prevention of inflammation without limitation. Oxidized lipid compounds without limitation are known to have many obstacles that would prevent one of ordinary skill in the art from accepting treating or preventing regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of exemplary animal inhibition of atherogenesis assay, *in vivo*, see pages 78-86 of the specification. There are no *in vitro* or *in vivo* working examples present for the prevention of inflammation by the administration of the instant oxidized lipid compounds of the instant invention.

The breadth of the claims

The breadth of the claims is treating or preventing inflammation using the oxidized lipid compound without limitation. Moreover, there is no reasonable basis for assuming the instant oxidized lipid compounds embraced by the claims will share the same physiological properties.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what inflammation using any oxidized lipid without limitation, and patients would be benefited (i.e., treated or prevented) by the administration of the instant oxidized lipid compounds of the instant invention. It would furthermore then have to determine which of the claimed treatment or prevention of inflammation using the instant oxidized lipid compounds would provide treatment or prevention of inflammation without limitation, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which inflammation would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the oxidized lipid compounds of the instant claims for the treatment or prevention of inflammation without limitation. As a result necessitating one of skill to perform an exhaustive search for which oxidized lipid compounds without limitation, can be treated or prevented by what oxidized lipid compounds. As a result necessitating one of skill to perform an exhaustive search for which inflammation can be treated or prevented by what oxidized lipid compounds of the instant claims in order to practice the claimed invention.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds in regards to the treatment or prevention of inflammation without limitation, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by deletion of "preventing" and incorporation of the limitation "oxidized lipid" (i.e., Formula (I)) into claim 140 respectively, would obviate the rejection.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

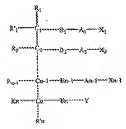
unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 91-139 and 179-192 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Harats et al. US 6,838,452. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

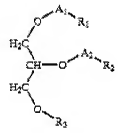
Applicants claim compound/compositions of formula (I), i.e.,

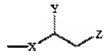


, wherein n is 1-6, B1 or B2 is oxygen, A1 or A2 is CR"R"', and Y is

alkyl, acyl, phosphoryl choline, phosphoryl ethanolamine, phosphoryl inositol, see claim 91 or 104.

Harats et al. '452 claims compounds/compositions of the formula, i.e.,



, wherein R1 is alkyl or  , A1 or A2 is CH2, and R3 is H, acyl, phosphocholine, phosphoethanolamine or phosphoinositol, see columns 40-42.

The difference between the instant claims and Harats et al. '452 is that the instant variable n is 1-6, while Harats et al. '452 represents 1 at the same position. Harats et al. '452 compounds overlap with the instant invention.

One having ordinary skill in the art would find the instant claims 91-139 and 179-192 prima facie obvious **because** one would be motivated to employ Harats et al. '452 compounds to obtain the instant compounds of Formula (I). Dependent claims 92-139 and 179-192 are also rejected along with claim 91 under the obviousness-type double patenting.

The motivation to obtain the claimed compounds derives from known Harats et al. '452 compounds would possess similar activity (i.e., compositions) to that which is claimed in the reference.

Claim Objections

5. Claims 184-185, 191-192 and 198-199 are objected to containing a typographic error respectively. A symbol "." is missing at the end of each claim. Correction is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1628

June 10, 2010